

IN RE THE MATTER OF:

Eric Marcoux, Senior Quality Assurance Manager  
Red Robin Gourmet Hamburgers  
6312 S. Fiddler's Green Circle, Suite 200N  
Greenwood Village, CO 80111

Re: Variance Request Dated August 18, 2009 and Section 195,  
Reduced Oxygen Packaging (ROP); criteria

Order to Deny a Variance

You are hereby notified that based on the recommendation of the Food Protection Program, Indiana State Department of Health (ISDH), and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be denied to Red Robin Gourmet Hamburgers, 6312 S. Fiddler's Green Circle, Suite 200N, Greenwood Village, CO 80111. A follow-up letter requesting more information on this request was sent on February 17, 2010 by certified mail asking for the information detailed below. The letter was signed for and no response was received to the questions.

Therefore, this variance denial is based on the variance application submitted on August 18, 2009, # 24, 2009. As a result of this action, all reduced oxygen packaging of food at restaurants under your control must cease unless in compliance with the requirements stated in 410 IAC 7-24-195, the Retail Food Establishment Sanitation Requirements.

Order

This **VARIANCE DENIAL** is based on the following criteria:

- The application was incomplete in that supporting documentation to demonstrate how your proposed plan would be implemented was not submitted. Examples of supporting documentation are, but not limited to, the following:
- The proposal did not provide the finished pH and/or water activity (Aw) of the 9 products listed on page 3 of the variance request.
- An example package label for each product was not provided.
- In light of the scientific study provided with the request indicating some strains of *Clostridium botulinum* are capable of toxin production at 3.3C (37.9F), the proposal did not explain how, in addition to the twice/day ambient storage cooler temperature checks, products being cooled and stored would be continuously monitored to assure product temperature is maintained at 41F or less.

- The proposal did not explain product storage/service handling in a way which specified whether or not the 9 sealed-packaged products prepared at a site would always be stored at that site and used at that site, or if items be would be stored/shared/sold to other sites, for example, shipped to other restaurants.
- The proposal did not specify if the cooked products are intended to be “hot filled” into the packaging, and if such were the case, a modified flow diagram and HACCP Plan, including the method and equipment for assuring that product temperature will be maintained at 135 F or higher, was not included.
- The proposal did not fully explain the significance with meeting the very specific time and temperature parameter of 176 degrees F for 10 minutes. Questions remained as to if all of the ingredients would be cooked together and the entire batch cooked to this time and temperature, or if the chicken would be cooked separately then added to the mixture, with the resulting product cooked to 176 F for 10 minutes. The proposal did not indicate what type of temperature measuring device would be used and how its accuracy is determined.
- The proposal was not adequately descriptive as to the measures which would assure that ROP product would receive a thorough reheat step since the products would look just like other foods that are ready-to-eat (RTE).
- The proposal did not indicate if the initial state of the ground beef patties is raw, precooked and/or frozen.
- The proposal did not explain why packaging and holding steps are not listed as critical control points (CCPs) and holding is not listed as a process step.
- A flow diagram and information were not provided related to the specific handling of the three products (from page 3 of the HACCP Plan) which are sealed-packaged, but not cooked.
- Materials provided in the request do not give specific information on training elements, such as how the training will prohibit bare hand contact with ready-to-eat food or the content of the ROP training. The proposal does not explain how specific points addressing these critical limits and control points will be covered.
- The proposal did not demonstrate how sealed-packaged activities for the 9 food products listed in the request would be separated by time or space from activities being conducted by employees working on other tasks within the facility.
- The proposal did not explain the HACCP Plan record retention for the 9 listed products and who specifically would be responsible for completing the documents and overseeing the monitoring and verification of the records.
- A question remains as to if the seal-package date is the same date as preparation.
- A question remains as to how often products would be made and packaged, including how large the batch sizes would be.

- On pages 4 and 5 titled "Chubbing HACCP Plan for *Clostridium botulinum*, Hazard Analysis/Preventive Measures": Temperature control and shelf life are listed as the two barriers to controlling of *Clostridium botulinum* growth and toxin production; however, the proposal did not provide sufficient documentation to support a 9 day hold time as a second barrier. The article submitted as scientific data merely states that a short shelf life is recommended for products that rely only on refrigeration temperature for preservation. The proposal did not explain how the included article supports a short shelf life for the products and processes of Red Robin.
- The proposal did not explain (from page 2, entitled "HACCP Plan, Product Description: The South West Pasta Sauce") why butter is not listed as being a product that is held cold or indicated to be a potentially hazardous food.

**If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §40-21.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:**

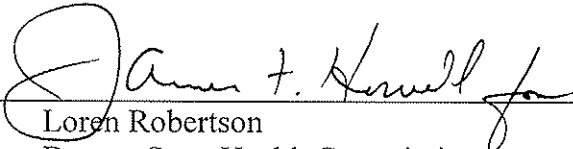
- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

**Your request for review or stay of effectiveness must be filed in writing with the State Health Commissioner, 2 North Meridian Street, Indianapolis, Indiana 46204, on or before April 19, 2010. If no request for review or stay of effectiveness is filed by April 16, 2010, this decision shall become final.**

DATED AT INDIANAPOLIS, INDIANA, THIS 31<sup>st</sup> DAY OF MARCH, 2010.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY DENY A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

GREGORY N. LARKIN, M.D.  
STATE HEALTH COMMISSIONER

By:   
Loren Robertson  
Deputy State Health Commissioner  
Indiana State Department of Health

cc: ISDH Food Protection Staff  
ISDH Office of Legal Affairs  
Local Health Departments in Indiana